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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,687	01/29/2004	Robert G. Ulrich	Army140D	8007

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U.S. Army Medical Research
and Materiel Command
504 Scott Street
Fort Detrick, MD 21702-5012

EXAMINER

ALLEN, MARIANNE P

ART UNIT PAPER NUMBER

1647

DATE MAILED: 08/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/767,687	Applicant(s) ULRICH ET AL.	
	Examiner Marianne P. Allen	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-9,15-18,24-26,32-34,40-44,50-53,59-62 and 68-102 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1, 7-9, 15-18, 24-26, 32-34, 40-44, 50-53, 59-62, 68-102.

DETAILED ACTION

Claims 2-6, 10-14, 19-23, 27-31, 35-39, 45-49, 54-58, and 63-67 have been cancelled by preliminary amendment. Claims 100-102 have been added by preliminary amendment. Claims 1, 7-9, 15-18, 24-26, 32-34, 40-44, 50-53, 59-62, 68-102 are pending.

Applicant is advised that several of the pending claims depend upon cancelled claims.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 7, 15, 24, 32, 40, 50, 59, and 68, drawn to nucleic acids encoding toxic shock syndrome toxin-1, classified in class 536, subclass 23.1.
- II. Claims 8, 16, 25, 33, 41, 51, 60, and 69, drawn to nucleic acids encoding Staphylococcal enterotoxin C1, classified in class 536, subclass 23.1.
- III. Claims 9, 17, 26, 34, 42, 52, 61, and 70, drawn to nucleic acids encoding Streptococcal pyrogenic exotoxin A, classified in class 536, subclass 23.1.
- IV. Claims 72 and 76-79, drawn to a Staphylococcal enterotoxin A toxin, classified in class 530, subclass 324.
- V. Claims 73 and 80-84, drawn to a Staphylococcal enterotoxin B toxin, classified in class 530, subclass 324.
- VI. Claim 74, drawn to a staphylococcal toxin shock syndrome toxin-1 toxin, classified in class 530, subclass 324.
- VII. Claim 75, drawn to a Staphylococcal enterotoxin C1 toxin, classified in class 530, subclass 324.

- VIII. Claims 85-87, drawn to methods of diagnosis and diagnostic kits, classified in class 435, subclass 7.1.
- IX. Claims 88-95, drawn to vaccines, classified in class 424, subclass 184.1.
- X. Claim 96, drawn to a method of treating a bacterial infection by administering a vaccine, classified in class 424, subclass 184.1.
- XI. Claim 97, drawn to a method of treating a bacterial infection by administering an antibody, classified in class 424, subclass 130.1.
- XII. Claim 98, drawn to a method of treating a bacterial infection by administering a protein, classified in class 514, subclass 12.
- XIII. Claim 99, drawn to a method for treating disease by modulating T cell subsets, classified in class 435, subclass 325.
- XIV. Claims 100-102, drawn to nucleic acids encoding Staphylococcal enterotoxin B, classified in class 536, subclass 23.1.

Claims 1 and 18 link(s) inventions I, II, and III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1 and 18. Claims 43-44, 53, and 62 are dependent upon claim 18 and will be examined with the elected invention.

Claim 71 link(s) inventions IV, V, VI, and VII.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an

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allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

If applicant elects any of inventions VIII-XIII, a further election is required. The claims of these inventions are generic to a plurality of disclosed patentably distinct species comprising SPEa, SEB, SEA, TSST-1, and SEC-1. Each of these superantigen toxins is a structurally and functionally distinct product which is capable of separate manufacture, use, and sale. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 85, 88, 96, 97, 98, and 99 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The inventions are distinct, each from the other because:

Inventions I-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products of inventions I-VII, IX, and XIV are structurally and functionally different and the methods of inventions VIII and X-XIII have different starting materials, methods steps, and goals. Each of the products can be shown to be distinct from each of the methods as the product is either not used by the method or can be used in multiple methods.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification and the inventions require a different field of search, particularly with respect to the non-patent literature (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected

process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

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specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marianne P. Allen

Marianne P. Allen
Primary Examiner
Art Unit 1647

8/11/06

mpa